REMARKS

Claims 1, 3-6, 9, 10, 13-18, 20, 21, 24-28, 30-39, and 42-53 are pending and stand rejected. Claims 32 and 33 are withdrawn from consideration. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks. The amendments made to claims 1, 13, 24, and 34 do not encompass new subject matter and do not require an additional subject matter search.

Amendments to the Claims

Applicants present the following amendments for the sole purpose of expediting prosecution of the pending claims. It is understood that such amendments are made without prejudice, and do not amount to Applicants' acceptance of the Office Action's rejections. Applicants reserve the right to prosecute any of the former forms of the claims in a continuing application.

Claims 1, 13, 24, and 34 are amended to recite that viable tissue is harvested from healthy tissue. Support for this amendment can be found throughout the specification, for example at paragraphs 0059 and 0065. No new matter is added.

Rejections Pursuant to 35 U.S.C. §102

Claims 1, 3-6, 9, 10, 13-18, 20, 21, 24-28, 30, 31, 34-39, 42-44, 46-50, 52, and 53 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2003/078617 of Schwartz et al. ("Schwartz"). Applicants respectfully disagree with the Examiner's rejection.

Claim 1

Claim 1 recites a composite implant for repairing a tissue defect in a patient. The implant comprises a wedge-shaped porous tissue scaffold formed from a bioresorbable, synthetic polymeric material, and includes at least one pocket containing a *viable tissue*. Claim 1 further recites that the viable tissue is harvested from healthy tissue.

First, the tissue regeneration material disclosed by Schwartz is neither a *tissue* nor composed of a *tissue*. Although the Examiner asserts that "Applicants admit Schwartz disclose[s] using tissue as stated on page 2 of the remarks," Applicants have made no such admission. Applicants previously argued that "[a]lthough the tissue regeneration material (22) is *derived from natural tissue*, there is no teaching or suggestion in Schwartz that the tissue regeneration material is 'a viable tissue,' as required by claim 1." (See Response filed 2/18/08 at page 2, emphasis added). Even though Schwartz discloses a tissue regeneration material (22) that is derived from a natural tissue, the resulting material is not, itself, a "tissue." The term "tissue" is defined as "an aggregate of cells usually of a particular kind *together with their* intercellular substance that form one of the structural materials of a plant or an animal." (Merriam-Webster Online Dictionary *available at* http://www.merriam-webster.com/dictionary/tissue, emphasis added). The tissue regeneration material disclosed by Schwartz is extracellular matrix material that has been cleaned, disinfected, sterilized, and optionally cross-linked. (*See* Schwartz at Par. 0083). Thus the resulting tissue regeneration material contains only extracellular matrix material and not cells "together with their intercellular substance." Accordingly, the tissue regeneration material disclosed by Schwartz is not a tissue, as required by claim 1.

Second, the tissue regeneration material disclosed by Schwartz is not a "*viable* tissue." In response to Applicants' previous arguments, the Examiner argues that "there is no reason that the tissue of Schwartz cannot be considered to be 'viable' tissue that is capable of working." However, the Examiner's argument rests on the incorrect assertion that the plain meaning of the term "viable" is "capable of working." Applicants note that "'plain meaning' refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art." (*See* MPEP 2111.01(III)). In particular, "[i]t is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the 'ordinary' and the 'customary' meaning of the terms in the claims." (*Id.*). Thus, the plain meaning of the term "viable" is not merely the broadest dictionary definition of the term but rather the "broadest reasonable interpretation in light of the specification." (*See* MPEP 2111.01(I)). Indeed, "the patent disclosure serves to point away from the improper meanings and toward the proper meanings." (*See* MPEP 2111.01(III)). Moreover, even "general meanings

cleaned from reference sources, such as dictionaries, must always be compared against the use of the term in context." (*Id.*).

In contrast, the Examiner's assertions regarding the meaning of the term "viable" are not supported by the meaning given to the term by those of ordinary skill in the art, the use of the term in context, or even the dictionary definition of the term. The term "viable" is defined as "capable of living, developing, or germinating under favorable conditions." (The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004, *available at* Dictionary.com, http://dictionary.reference.com/browse/viable). Moreover, the instant application discloses various exemplary sources of viable tissue, all of which are tissue harvested from healthy tissue, as recited by claim 1. (*See e.g.* paragraphs 0059 and 0083 to 0096). The instant application also discloses that cells contained within the viable tissue are capable of migrating into the scaffold itself, as further recited by claim 1. (*See e.g.* paragraph 0059). Thus, when taken in the context of the instant application, the meaning of the term "viable" is more closely met by the dictionary definition of the term than by the meaning attributed by the Examiner. Accordingly, Schwartz fails to teach or suggest a *viable* tissue, as required by claim 1.

Schwartz also fails to teach or even suggest a composite implant including at least one pocket containing a *viable tissue* that is *harvested from healthy tissue.* The Examiner argues that Schwartz "shows (Fig. 23) that there is a tissue material 22 placed in a pocket or hollow interior or lumen." However, Schwartz actually teaches a "mass of tissue regeneration material 22." The tissue regeneration material (22) "encompasses naturally occurring extracellular matrix (ECM) materials that provide a collagen scaffold for tissue repair and regeneration." (*See* Schwartz at Par. 0083). As discussed above, the tissue regeneration material (22) formed from ECM materials is not a viable tissue as required by claim 1. Indeed, Schwartz explains that "the terms 'naturally occurring extracellular matrix' and 'naturally occurring ECM" are intended to refer to extracellular matrix material that has been cleaned, disinfected, sterilized, and optionally cross-linked." *Id.* A material that has been *sterilized* is clearly not *viable* according to the meaning that would be given to the term by those of ordinary skill in the art. Accordingly, Schwartz fails to teach or suggest that the tissue regeneration material is "a viable tissue," as required by claim 1.

Claim 13

Claim 13 recites a composite implant for tissue repair comprising a wedged shaped porous scaffold having at least one pocket therein. Viable tissue, such as minced tissue, sliced tissue, or slivered tissue is disposed within the scaffolds' pocket. Claim 13 further recites that the viable tissue is harvested from healthy tissue.

As discussed above with respect to claim 1, Schwartz fails to teach or even suggest a composite implant including *viable tissue* disposed within a pocket in the scaffold, or that the viable tissue is *harvested from healthy tissue*. The tissue regeneration material (22) taught by Schwartz is created by processing "naturally-occurring extracellular matrix" into "a scaffold for tissue repair and regeneration." *See* Schwartz at Par. 0083. The Examiner argues that "Schwartz et al. disclose that tissue is obtained and comminuted (i.e. mince, slice or sliver) to smaller fragments and then loaded between of within the pocket of the tissue scaffold." However, Schwartz does not teach or even suggest the use of viable tissue comprising at least one of minced, sliced, and/or slivered tissue fragments, as required by claim 13. The processing steps cited by the Examiner are used to process ECM to create a scaffold. (*See* Schwartz at Par. 0123). As discussed above, ECM is not viable tissue, and although the process of creating a scaffold from ECM includes a comminuting step, the result is processed ECM, not viable tissue.

Claims 24 and 34

Claims 24 and 34 recite methods for repairing defective tissue. The claimed methods comprise obtaining a viable tissue harvested from healthy tissue and loading the viable tissue, or fragments thereof, into at least one pocket formed by an opening in the sidewall of a tissue scaffold.

The Schwartz reference does not teach or suggest the claimed method for tissue repair. The Examiner argues that Schwartz "shows (Fig. 23) that there is a tissue material 22 placed in a pocket or hollow interior or lumen." However, as discussed above with respect to claims 1 and 13, Schwartz fails to disclose the use of *viable tissue* in a method for tissue repair. The "tissue material 22" disclosed by Schwartz is actually "cleaned, disinfected, sterilized, and optionally cross-linked" extracellular matrix material. *See* Schwartz at Par. 0083. Schwartz does not teach

or suggest obtaining a viable tissue harvested from healthy tissue or loading viable tissue into a pocket of the tissue scaffold. The tissue regeneration material (22) disclosed by Schwartz is produced by processing extracellular matrix materials. *Id.* The processed ECM is not *viable* tissue. Although Schwartz discloses that the processed ECM may be "seeded with living cells," the resulting tissue regeneration material does not contain viable tissue and is not, itself, a viable tissue. *See* Schwartz at Par. 0144. The addition of living cells to a sterilized extracellular matrix material does not produce a viable tissue. The resulting cell-seeded ECM is merely a convenient delivery vehicle for the cells seeded thereon.

Accordingly, independent claims 1, 13, 24, and 34 distinguish over Schwartz and represent allowable subject matter. Claims 3-6, 9, 10, 14-18, 20, 21, 25-28, 30-33, 35-39, and 42-53 are allowable at least because they depend from an allowable base claim.

Rejections Pursuant to 35 U.S.C. §103

Claims 45 and 51 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Schwartz. Applicants respectfully disagree with the Examiner's rejection.

At the outset, Applicants note that claims 45 and 51 incorporate the recitations of their respective base claims and thus distinguish over Schwartz for at least the reasons discussed above with respect to the base claims. In particular, independent claims 13 and 34, from which claims 45 and 51 depend, require that the minced, sliced or slivered tissue fragments are viable tissue fragments. Schwartz does not teach or even suggest forming fragments of viable tissue. Schwartz discloses that ECM materials are comminuted or shredded in the process of creating an ECM scaffold. *See* Schwartz at Par. 0122-0123. However, there is no teaching or suggestion in Schwartz that would lead one of ordinary skill in the art to utilize fragments of viable tissue, let alone fragments of viable tissue of the claimed particle size. Moreover, the processing steps cited by the Examiner are actually used to process ECM to create a scaffold, which is then seeded with cultured cells. Cultured cells are very different from fragments of viable tissue, and cells obtained through cell culture, even when seeded onto the tissue regeneration material disclosed by Schwartz, are not equivalent to viable tissue fragments obtained from body tissue.

The Examiner admits that "Schwartz fails to explicitly disclose the tissue fragments are of a particular size having the dimension of 0.5 mm^3 to 3 mm^3." The Examiner argues that Schwartz discloses "that the particle size can be any dimension and is not to be limited to particular dimensions, paragraph 122." However, paragraph 122 of Schwartz provides "a specific example of a process for fabricating an exemplary ECM foam." (Schwartz at Par. 0122). The Examiner relies on the disclosure of this process to argue that "Schwartz can be interpreted to suggest that dimensions can be modified according to the disclosure or Schwartz." However, as discussed above, Schwartz's tissue regeneration material is not a viable tissue. Moreover, the "procurement of comminuted ECM" as described by Schwartz and the corresponding disclosure in paragraph 0122 that "the invention is not limited to a particular size of ECM fiber material" suggests only that the size of ECM fibers can be modified. (*See* Schwartz at Par. 0122). The suggestion that the size of ECM fibers can be modified provides no suggestion that the size of viable tissue fragments can be modified to meet the requirements of claims 45 or 51. Schwartz therefore fails to teach or suggest viable tissue fragments, much less viable tissue fragments of the claimed size range.

Furthermore, in spite of the failure of Schwartz to provide a suggestion to use viable tissue fragments, the Examiner continues to argue that the claimed fragment size "would have been obvious to one of ordinary skill in the art...since such a modification only involves routine skill in the art" and that "optimization of dimensions of the tissue material would be within the skill of a scientist." Even if the failure of Schwartz to suggest the use of viable tissue fragments were ignored, the Examiner's arguments would still be incorrect. As shown by the previously cited Solov'ev reference, tissue fragment size is related to the success of an implant by a non-linear relationship; the optimization of which would not be a routine matter. Applicants note that the Solov'ev reference indicates that the success of an implant comprising tissue fragments is indeed dependent on a particular tissue fragment size, albeit a tissue fragment size that is also dependent on tissue type. Solov'ev also indicates that the functional activity of tissue fragments is not linearly related to fragment size. *See* Solov'ev at Fig. 2. The non-linear relationship between tissue fragment size and functional activity disclosed by Solov'ev indicates that selection of tissue fragment size for a given tissue type is not merely a routine matter. Therefore, the selection of the claimed tissue fragment size would not have been obvious to one of ordinary skill in the art.

Finally, tissue fragment size is critical to the success of an implant that uses tissue fragments. The Examiner asserts that "varying the size [of the tissue fragments] would not affect the function of the cells to carry out a process." The Examiner further clarifies this statement by explaining that "[t]he Examiner was not stating that the cells would achieve some desired result, but only that their capability to function would not be impeded." However, Solov'ev discloses that "fragments above 0.5 and below 0.4 mm exhibited lower functional activity." *See* Solov'ev at p. 979. The disclosure of Solov'ev shows that varying the size of a tissue fragment *does* impede the *function* of the cells and is therefore critical to the success of the implant. The Examiner's assertions are therefore incorrect and directly contradicted by the well established art at the time the invention was made.

Accordingly, claims 45 and 51 distinguish over Schwartz and represent allowable subject matter.

Conclusion

In conclusion, Applicants submit that all claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Dated: 9/2/2008

Respectfully submitted,

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